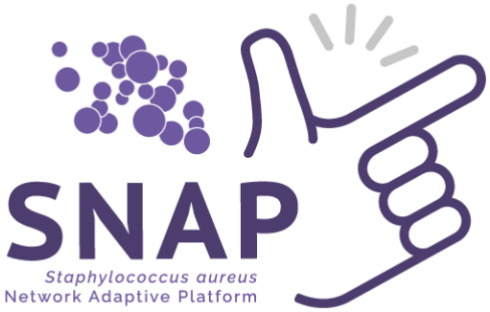


SNAP TRIAL

DATA SHARING POLICY AND ACCESS PROCEDURE

Version 1.0, DATED 13 FERBUARY 2024

1 TABLE OF CONTENTS

1.1 ABBREVIATIONS

Term	Definition
DSP	Data sharing policy
GCP	Good Clinical Practice
GCC	Global coordinating centre
GTSC	Global trial steering committee
UoM	University of Melbourne
DAAF	Data Access Application Form

1.2 DEFINITIONS

Term	Definition
Data Sharing Agreement	legally binding document that delineates the terms, conditions, and responsibilities associated with the exchange of data between parties. It defines the scope, purpose, confidentiality measures, to ensure secure and compliant data sharing
Data requesters/Investigator	individual, entity, or system that formally seeks access to and use of specific data, typically governed by legal or contractual agreements
Data custodians	individual or entity responsible for safeguarding and managing the security, access, and integrity of a specific dataset or database
De-identified data	information from which all personally identifiable elements have been removed or altered to prevent the identification of individuals
Data access application form	document used to formally request authorization for accessing specific datasets, detailing the purpose, scope, and intended use of the requested data

2 INTRODUCTION

The objective of data sharing is to enhance the value of datasets making them more valuable for research in various areas. Additionally, it encourages collaboration among researchers, promoting further research opportunities. By sharing data, researchers can avoid redundant efforts, saving time, and resources that would otherwise be invested in reproducing existing datasets. Furthermore, sharing data is essential for rapidly translating research outcomes into knowledge and procedures that lead to better human health outcomes.

The approach to disseminating scientific data must be responsible and consider various factors including, legal, regulatory, ethical, and commercial constraints. The National Statement on Ethical Conduct in Human Research, 2007 (updated 2018), outlines the requirements for the collection, use, and management of data and information pertaining to research with human participants.. Unless there is a valid reason for doing so, researchers are strongly encouraged to share data generated by their research. In the context of clinical research involving individual participants, considerations must be given to:

- Participants having provided informed consent to have their data shared.
- The risk of participant re-identification from shared de-identified datasets
- The risk of data being misused or misrepresented.
- Data security measures and protection laws
- Fostering transparent communication with the participant regarding how their data will be shared.

Furthermore, Good Clinical Practice (GCP) emphasizes that researchers must engage in data management planning for their research studies, encompassing arrangements for sharing or providing access to published data. The Australian Code for the Responsible Conduct of Research 2018 defines transparency in research and research data management as declaring interests and reporting the methodology, data, and findings applicable to all research studies involving these aspects. This involves sharing and communicating research methods and findings openly, accurately, and in a responsible manner.

This data-sharing policy (DSP) ensures SNAP has transparent processes in place to enable the appropriate sharing of SNAP-related data in a research culture that increasingly encourages access to publicly funded research data.

3 SNAP DATA SHARING PRINCIPLES

This DSP pertains to all studies conducted by SNAP and is guided by the principles of responsible data sharing in clinical trials established within the University of Melbourne (Australia), and national research and research funding bodies such as the NHMRC, UK MRC, Canadian IHR, and the European Union. Furthermore, this DSP applies to all members of the SNAP trial community: all trial committees and working groups, management teams, and the broader SNAP trial group (site teams and investigators). The guidelines outlined in this policy apply to requests for sharing data, both for ongoing studies and those that have been completed.

This data dissemination serves the purpose of encouraging physicians, patients, and healthcare providers to make well-informed treatment decisions and to foster advancements in scientific understanding that have a positive impact on society at large. Our commitment lies in ensuring that

our clinical study information is accessible to patients, medical practitioners, and researchers, all while upholding the principles of patient privacy and safeguarding commercial confidentiality. Achieving this objective involves productive collaborations with various individuals dedicated to promoting data-sharing initiatives. We strongly believe that disclosing our research results and data is instrumental in fully recognizing the public health advantages derived from our research.

SNAP's key principles of data sharing include the:

1. SNAP is committed to ensuring information generated in our studies is used for the benefit of patients and society.
2. SNAP takes all necessary steps to safeguard patient privacy, in compliance with the principles of GCP and applicable laws and regulations.
3. As the data custodians, SNAP's data sharing approach is aligned with the guidelines and requirements of the University of Melbourne, and national research and research funding bodies such as the NHMRC, UK MRC, Canadian IHR, and the European Union.
4. SNAP reserves the right to protect our commercially sensitive information or that of third parties with whom we have contractual obligations.
5. SNAP collaborates with a range of organisations and individuals to support and advance the sharing of data and information.

It is with these principles in mind that we have designed this policy to guide the responsible sharing of data across diverse study designs, fostering the advancement of scientific knowledge while maintaining ethical and transparent practices.

4 DATA RESPONSIBILITIES AND OWNERSHIP

The SNAP Global Coordinating Centre (GCC) is directly responsible for implementing the Data Sharing procedures set out in this policy to ensure that data is shared appropriately in accordance with the research study requirements. This includes but is not limited to;

- ethical and other regulatory approvals.
- participant consent.
- SNAP Trial policy and requirements and.
- the terms and conditions of any funding agreements where applicable.

Whilst the SNAP GCC will be the initial point of contact for all initial requests to access research data, the Global Trial Steering Committee (GTSC) will ultimately oversee all requests for data access/transfers, and if applicable, define the circumstances under which the data will be shared.

The GTSC will:

- review, by way of approving or rejecting, all data access requests submitted by data requesters about this policy;
- collaborate with external researchers to establish the scope, purpose, and duration of data sharing, aligning with ethical guidelines and legal regulations. Specific restrictions on data use, such as preventing re-identification and commercial use, are defined to protect participant privacy and trial integrity.
- address issues of intellectual property and authorship to ensure proper credit for contributions.

The SNAP regional trial management teams within the GCC will be informed of the data request/s that pertain to region-specific patient data by the SNAP GCC. This process is to ensure that the request aligns with the regional-specific policies regarding patient privacy and confidentiality, patient consent, regulations, and data-sharing agreements.

Currently, the SNAP GCC is the University of Melbourne (UoM), which acts as the data custodian for the SNAP trial. The data custodian is defined as the individual or organisation with the responsibility for the relevant collection of data and ensuring access to datasets is done in a controlled and authorised manner.

5 DATA SHARING AGREEMENT

Upon approval of the data request, the data requester/investigator must be familiar with the terms and conditions of data use and data sharing expectations outlined in this policy and adhere to the following conditions:

1. Data requesters/investigators can only use the data they receive for the approved research project. If they want to use it for a new project, they need to submit a new data request application.

2. Data requesters/investigators must acknowledge the SNAP trial identifier and data source and ensure that they keep individual participant data confidential. Sharing the data is limited to data requesters/investigators outlined in the data request document; requests from others should be directed to GTSC.

3. A fee might be applied where the dataset/s requested requires conditional formatting and other processing requirements outlined in the data request form.

4. SNAP's policies, including Privacy and Confidentiality, Clinical Data Transfers, and Informed Consent, apply to data use and transfer. Authorship details will be discussed before data release and should adhere to the policies outlined in the SNAP Authorship and Publication document.

5. A contract will be established between the data custodian and relevant parties for data release. This acknowledges compliance with collaborative agreements between SNAP and the data requester/investigator institution from which they are from.

6. Data requesters should provide information about the funding sources, if applicable, for their proposed work, including updates on subsequent funding secured after receiving the shared data.

7. The data requesters or investigators, along with their research team, must refrain from making any attempts to personally identify individuals from the provided data. If the requester or any member of their research team inadvertently identifies an individual, they are strictly prohibited from recording such identifiable information, disclosing the identification to others, or attempting to contact the individual. Any instances of accidental identification must be promptly reported to trial sponsors.

6 DATA AVAILABILITY POLICY

A. Following publication of domain-specific results:

i. De-identified patient data may be made available after publication of domain-specific results. All requests for data must be accompanied by;

- a formal request,
- a study proposal with a clear statement of aims and hypotheses, and
- a statistical analysis plan.

Requests for access to the dataset(s) relating to domain-specific results will be assessed by the Global Trial Steering Committee (GTSC). If a proposal is approved, a signed data transfer agreement will be required before data sharing.

B. Before publication of domain-specific results:

i. Post-randomisation outcome data stratified by randomised intervention: The SNAP trial will not release data that includes post-randomisation outcomes stratified by intervention until a domain conclusion has been publicly declared for the relevant domain.

ii. Post-randomisation outcome data not stratified by intervention: As a default, the SNAP trial will not release data that includes post-randomisation outcomes regardless of stratification by intervention.

However, where there is compelling justification, the GTSC may consider requests for the release of trial outcomes without stratification by interventions. These will be treated on a case-by-case basis and will require strong and convincing justification and clear strategies to mitigate risks to trial integrity.

iii. Data and analyses arising from registry-only participants may be accessed and published before publication of the primary clinical trial results. However, specific data requests will need to be reviewed and approved by the GTSC.

iv. Requests for a mixed dataset (platform and registry data): Platform considerations (i & ii) will apply to these data requests.

7 DATA REQUESTS

7.1 APPLYING TO ACCESS DATA

Where research data will be available for sharing, the SNAP Trial regional management team must outline this in the study-specific DSP, before collecting/generating any data for the study.

Initial inquiries regarding access to data should be directed to the SNAP GCC, where the data was generated.

Data Requesters must formally request access to datasets by submitting a Data Access Application Form (DAAF) to the GCC at the following email: snap-trial@unimelb.edu.au. The DAAF asks for information intended to help facilitate a review of the request. This information includes the research proposal, statistical analysis plan, ethical review status, and funding status of the proposed research, if applicable. Received DAAFs will be screened and forwarded to the GTSC for assessment and review. If the data requester/investigator wants to discuss their request before officially applying, they can contact the SNAP GCC: snap-trial@unimelb.edu,au

7.2 REVIEWING DATA ACCESS APPLICATION

The request will be reviewed with the following criteria in mind:

- The value of the research proposal to medical science and or patient care.
- The ability of the proposed statistical analysis plan to meet the scientific objective of the research proposal.
- Potential conflicts of interest that may impact on the research proposal and measures to manage these conflicts.
- The qualifications and expertise of the research team to conduct the proposed research.
- SNAP staff resources required to process the request.
- Risk of participants being re-identified, or their privacy being breached.
- Capacity of the Data Requester to maintain data security.
- For Data Requesters who have successfully applied for other SNAP datasets: failure to abide by the conditions of the previous transfer.
- Risk of datasets being used to misrepresent SNAP research or bring SNAP's scientific credibility into disrepute.

The GTSC has an established internal review process for approving and/or rejecting research data requests. The request is reviewed against internal assessment and either approved or rejected on that basis. The GTSC should have the joint expertise to assess the scientific merit, ethical acceptability, legal implications, and feasibility of the request in providing the requested data. Outcomes of the review of each data request application will be recorded on the DAAF and a log of all requests, whether approved or denied or further information required will be maintained by the Snap Trial regional management team.

7.3 DATA RELEASE

Release of the requested dataset should occur promptly following approval of the request and signed data access application at SNAP, typically within 2 months.

The dataset will be released as a Data Pack i.e. a prepared package of data and metadata to be provided to a requester by the organisation. Accompanying the Data Pack should be the Data Dictionary and the signed DAAF.

The Data Pack will be provided via a secure transfer channel (See Appendix 12.2 Data Information). Information and instructions on how the data sharing procedure is utilized within this channel will be sent to the data requester upon data release.

8 TIMELINE FOR REVIEWING AND ACKNOWLEDGING A DATA ACCESS APPLICATION

All data access applications will be reviewed at the next scheduled monthly GTSC meeting from the date when the data access application was received. Data Requesters who have submitted a Data Access Application will be notified of the outcome by the SNAP GCC within 10 working days from the meeting date. The acknowledgment should indicate the decision (approved/rejected), or whether additional information is required from the Data Requester before a decision can be made.

Incomplete Data Access Applications Forms: Incomplete DAAFs should be returned to the Data Requester with an instruction to complete and resubmit the form.

Accepting a Data Access Application: If the GTSC approves an access request, the Data Requester will be notified in writing and a timeline provided for when and how the data will be made available. The outcome of the data request must be logged. All approvals are subject to review. Where demand exceeds the availability of staffing resources to make the data available, access will be prioritised by the SNAP Trial management team on scientific merit.

Rejecting a Data Access Application: If the GTSC rejects a data access application, the Data Requester will be notified in writing and be provided with an explanation/justification as to why the request was rejected.

Subsequent Data Requests Post Rejection: Based on any feedback provided, a Data Requester may amend their original data access request application and submit a new access request following rejection.

9 DATA SECURITY, ENCRYPTION, AND ACCESS CONTROL

Data security, encryption, and access control are necessary for data sharing within clinical trials to safeguard sensitive patient information, ensure research integrity, and maintain regulatory compliance. The SNAP trial contains confidential health records, personal identifiers, and private research insights where robust data security measures, such as encryption during transmission and storage, are required to safeguard this information from unauthorized access and potential breaches. Furthermore, SNAP implements access control mechanisms to establish strict permissions, ensuring that only authorized personnel can access, modify, or analyse the data.

SNAP implements the following practices to safeguard patient information as follows:

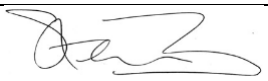
- Automatic Data De-Identification and Anonymization: Remove or replace identifying information from the dataset to ensure that individuals cannot be linked to their data.
- Anonymize data so that even if certain characteristics are present, they cannot be traced back to specific individuals.
- Limited Data Sharing: Only share the minimum necessary data required for the intended research purpose.
- Access Controls and Authorization: Implement strong access controls to ensure that only authorized individuals or entities can access the shared data.
- Use role-based access, where different levels of access are granted based on the user's role and need.
- Secure Data Transfer: Use encryption protocols (such as SSL/TLS) during data transfer to prevent interception and unauthorized access.
- Use secure file transfer mechanisms and platforms to ensure data is transmitted safely.
- Data Encryption: Encrypt data both during storage and transmission to protect it from unauthorized access.
- Secure Hosting Environments: If data is hosted on a server, use secure hosting environments.
- Secure Disposal: Ensure that any physical or digital copies of data that are no longer needed are securely disposed of to prevent accidental exposure.

10 DATA SHARING STATEMENT

Deidentified patient data can be made available (participant data with identifiers, data dictionary), following publication of study results. Requests for data sharing must be accompanied by a formal request, a study proposal with a clear statement of aims and hypotheses, and a statistical analysis plan. Applications will be assessed by the SNAP Global Trial Steering Committee. Applications from investigators with suitable academic capability to conduct the proposed work will be given consideration. Proposals may require approval from the relevant ethics committees or institutional review boards. If a proposal is approved, a signed data transfer agreement will be required before data sharing.

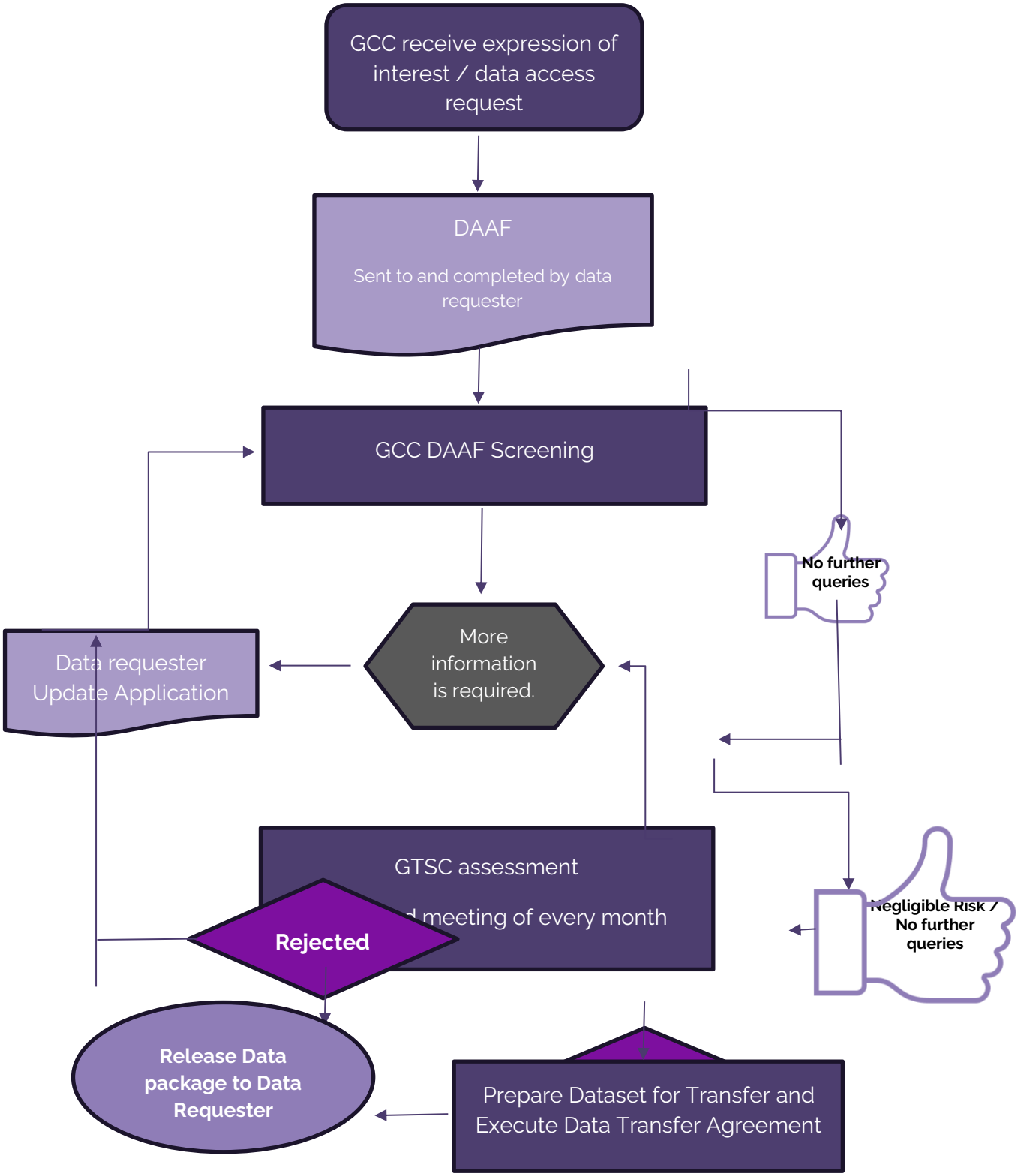
11 DOCUMENT HISTORY

VERSION	DATE	REASON FOR REVISION
1.0	13 February 2024	Initial version

Approval				
	Name	**Position**	**Signature**	**Date**
Authors	Jay Keatley	Data Coordinator		13 Feb 2024
Reviewed by	Michelle Reading	Global Trial Manager		13 Feb 2024
Approved by:	Steven Tong	Chief Investigator		13 Feb 2024
	Josh Davis	Chief Investigator		13 Feb 2024

12 APPENDIX

12.1 DATA ACCESS PROCEDURE (FLOWCHART)



12.2 DATA INFORMATION

SNAP Identifier (NCT):	NCT05137119
Data collection:	Patient Demographics Clinical Assessment Medical History Laboratory tests Imaging and diagnostic tests Follow-up Data Safety Events
Classification:	Restricted
File Format (Structured):	Excel (.xlsx, .csv)
File naming:	*datasetname_date_filenumber. filetype*
Data size:	~100KB - 5MB
Method of transfer:	MediaFlux
Frequency of transfer:	One-off , multiple ad-hoc
Data access:	Authorized access only
Storage facility:	Network File Share (Research-NAS)

12.3 DATA ACCESS APPLICATION FORM (DAAF)

Staphylococcus Aureus Network Adaptive Platform Trial (SNAP)

Data Access Application Form

Instructions for Data Requesters

1. Data Requesters should discuss their application with the SNAP Global coordinating centre (GCC) to understand the suitability, availability, and modes of collaboration and access to SNAP Trial data.
   The following SNAP trial documents should be read before completing this form:
   - Data Sharing Policy
   - Authorship & Publication Policy
2. Data Requesters must complete and submit this application form to the GCC via email (see below)

   - Please also include relevant supporting information, including, where relevant: ethical approval, and applicants/investigators' CV

3. The Global Trial Steering Committee (GTSC) will review requests in order of receipt and respond with an approved or not approved decision, or a request for further information.

   - If approval is given, a data access application form must be finalised and signed off by the data requester, GTSC, and data transfer coordinator before the requested data is transferred.

Email completed application forms to:
snap-trial@unimelb.edu.au

SNAP Trial Data Access Application Form	
Section 1: Applicant Details	
Date of Application:	Click or tap here to enter text.
Name of Applicant/Principal Investigator:	Click or tap here to enter text.
Applicant Institution/Affiliation:	Click or tap here to enter text.
Email Address:	Click or tap here to enter text.
Other investigators (Names):	Click or tap here to enter text.
With whom have you previously discussed this data request?	☐ SNAP GTSC member/s Name/s: Click or tap here to enter text. ☐ SNAP Global coordinating centre member/s Name/s: Click or tap here to enter text.
Has this project already been approved by the Global TSC? ***For example, a sub-study that has already undergone GTSC review and approval***	☐ Yes – Date of approval: __ / __ /____ ☐ No

Section 2: Ethics Review / Approval

PLEASE CONSIDER the following when determining if additional ethical approval via a separate ethics submission or by an amendment in the current SNAP trial approval is required:

Platform (randomized) trial dataset:

All secondary analyses of trial data will require additional assessment by the trial management group to determine if additional ethics is required.

Registry Dataset:

Analysis of the registry dataset has been considered and approved as part of the primary SNAP ethics application for the following purposes:

- **Assessing quality of care and outcome** "The primary objective of the registry will be to assess indicators of quality of care and 90-day mortality for patients with SAB at participating sites. Results from the SNAP trial will be incorporated as quality-of-care indicators to provide a measure of research translation at participating sites. Regular casemix-adjusted feedback on patient outcome and quality of care indicators will be provided to participating sites to encourage optimal management of all patients."
- **Monitoring the use of trial interventions among non-randomised patients** "The registry dataset will also be used to monitor the proportion of non-enrolled patients across participating sites who receive SNAP trial interventions as part of usual care. These results will be used to monitor changes in practice that occur during the lifetime of the trial, including the impact of site participation in the SNAP trial on usual care, and the implementation of findings declared at platform domain conclusions."
- **Assessing trial representativeness** "The registry will also seek to describe the representativeness of patients enrolled in the SNAP trial by collecting epidemiological and disease-specific descriptors of patients with SAB who are not enrolled in the trial. These data will also be used to examine outcome differences between comparable randomized and non-randomised patients."

If your project intends to use/analyse data beyond the scope listed above, you may need additional ethics. Please discuss with your regional management team

Has the Project/Study been submitted for ethical review and obtained approval:	☐ N/A (i.e. no additional approval required) Approved by ethics as: ☐ Amendment to the SNAP protocol, or ☐ Separate application • Name of Ethics Committee: Click or tap here to enter text. • Reference number (if applicable): Click or tap here to enter text.

	• Date of approval: Click or tap here to enter text. ☐ Submitted, pending approval • Name of Ethics Committee: Click or tap here to enter text. • Reference number (if applicable): Click or tap here to enter text. ☐ Not yet submitted for ethical approval

Section 3: Project summary	
Applicant Project/Study Title:	Click or tap here to enter text.

Provide a brief description of the project background, objectives, analysis plan, summary of any relevant data that support the proposed study, and other supporting material/references. [Max: 1000 words]

☐ Protocol approved by the Global TSC as part of the substudy approval process attached

Click or tap here to enter text.

Section 4: Data Request

The SNAP global coordinating centre at the University of Melbourne, Australia, wishes to acknowledge its explicit commitment to maintaining the confidentiality, safety, security, and integrity of all patient data. In adherence to relevant ethical principles and regulatory guidelines, we declare that no clinical trial data will be shared or disclosed to an external entity that could compromise trial integrity.

SNAP TRIAL- DATA SHARING OVERARCHING POLICY

A. Following publication of domain specific results:

i. De-identified patient data may be made available after publication of domain-specific results. All requests for data must be accompanied by:
   - a formal request,
   - a study proposal with a clear statement of aims and hypotheses, and
   - a statistical analysis plan.

   Requests for access to the dataset(s) relating to domain-specific results will be assessed by the Global Trial Steering Committee (GTSC). If a proposal is approved, a signed data transfer agreement will be required before data sharing.

B. Prior to publication of domain specific results:

i. Post-randomisation outcome data stratified by randomised intervention: The SNAP trial will not release data that includes post-randomisation outcomes stratified by intervention until a domain conclusion has been publicly declared for the relevant domain.

ii. Post-randomisation outcome data not stratified by intervention: As a default, the SNAP trial will not release data that includes post-randomisation outcomes regardless of stratification by intervention.
   However, where there is compelling justification, the GTSC may consider requests for the release of trial outcomes without stratification by interventions. These will be treated on a case-by-case basis and will require strong and convincing justification and clear strategies to mitigate risks to trial integrity.

iii. Data and analyses arising from registry-only participants may be accessed and published before publication of the primary clinical trial results. However, specific data requests will need to be reviewed and approved by the GTSC.

iv. Requests for a mixed dataset (platform and registry data): Platform considerations (i & ii) will apply to these data requests.

The data requester is responsible for protecting the confidentiality of the data and not sharing this data with third parties.

What Data Elements are Required? *Provide a broad description of variables or provide an attachment with a detailed description of the data sets and/or other information requested, if available.*	☐ Platform dataset only (randomised participants) ☐ Registry dataset only (non-randomised participants) ☐ Both datasets
Is data from all participants required or only from a subset?	☐ All participants OR Specific domains: ☐ All domains ☐ Backbone Domain ☐ Adjunctive Domain ☐ Early Oral Switch Domain ☐ PET/CT Domain Specific subsets: ☐ Subset, please specify: ☐ Adults (18+ years) ☐ Children (<18 years) ☐ Region, specify: Click or tap here to enter text. ☐ MSSA ☐ MRSA ☐ PSSA ☐ Other, please specify: Click or tap here to enter text.
Does your request relate to specific data collection variable/s used in the SNAP trial? *Please refer to SNAPs Data description for variables available, and list these accordingly*	☐ Yes ☐ No, I require all variables related to the data set/s required above If yes, please refer to the data description in the appendix and select the appropriate variables
Frequency of data extracts:	☐ Once-off request Landmark for data extract (date or other): Click or tap here to enter text. ☐ Recurrent request Landmark for first data extract: Click or tap here to enter text.

	Frequency of subsequent extracts: Click or tap here to enter text.
Data Format:	Datasets will be provided in .CSV file format *For other requirements, please discuss with the SNAP global management team*

Section 5: Data Security	
How and where will the data be stored?	Click or tap here to enter text.
Names of individuals with authorized access to the data	Click or tap here to enter text.
How will access to the transferred data be restricted to authorized personnel only?	Click or tap here to enter text.
What security measures will be in place to protect data?	Click or tap here to enter text.
Describe the preferred method of data transfer (e.g., secure FTP, encrypted email, dedicated secure network):	Click or tap here to enter text.
Detail any encryption methods used in the process of receiving the data:	Click or tap here to enter text.
How long will the data be retained?	Click or tap here to enter text.
And (if relevant) how will the data be securely and irreversibly destroyed?	Click or tap here to enter text.
Provide any additional information or instructions related to data security not covered above:	Click or tap here to enter text.

Section 6: Funding	
Do you have funding for this research project?	☐ Yes ☐ No
If yes, please provide details of the grant/award/funding body to support your proposed work:	Click or tap here to enter text.
If no, specify how the work will be resourced, including whether the submission of a grant is anticipated:	Click or tap here to enter text.

Section 7: Form sign-off (Data requester)	
The proposed protocol/study will be discussed by the SNAP Global Trial Steering Committee, who will recommend SNAP investigators who should be included as authors for associated publications. These recommendations will be communicated to sub-study investigators for agreement prior to data transfer. ☐ Please confirm that you have read and agree to comply with the SNAP Publication & Authorship policy.	
As Principal Investigator: ▪ I agree to acknowledge the SNAP participants and research team as the source of data used in any publication or presentations of the research at any scientific meetings. ▪ I will forward a copy of any publication or presentation to the SNAP Global Trial Steering Committee ▪ I confirm that I have completed all sections of the application form, read, and understood the Standard Conditions outlined above and that all required supporting documents have been provided.	
Are the following supporting documents attached to this Application? *Please check all that are attached.*	Evidence of Ethical Review and approval ☐ CV & GCP of the investigator ☐ Approved Protocol ☐ Additional documentation: Click or tap here to enter text.
_____ ***Principal Investigator's signature***	_____ ***Date (DD-MMM-YYYY)***

Email a copy of this completed form and supporting documents to the SNAP trial management (snap-trial@unimelb.edu.au)

Section 8: Form sign-off (Data review/transfer)

Data must be accessed/shared following the study's Data Sharing and Access requirements, including all relevant SNAP policies and procedures, the SNAP Data Sharing Policy and Access Procedure, and must also be consistent with the Protocol, Patient Information and Consent Form (PICF) and the terms of any funding, collaboration agreements or other legal agreements governing the project.

Section 8a: Review by GTSC

Request reviewed by:	Click or tap here to enter text.
Date of review:	Click or tap here to enter text.
Have the region leads been notified of data sharing where appropriate?	Click or tap here to enter text.
Has the data request been approved?	☐ Yes, approved Comments: Click or tap here to enter text. ☐ Request not approved Comments: Click or tap here to enter text.
Date applicant was notified of outcome:	Click or tap here to enter text.

_____ _____

GTSC signature ***Date (DD-MMM-YYYY)***

Section 8b: Data Transfer

Name of the person who prepared the dataset for transfer: **Role:**	Click or tap here to enter text. Click or tap here to enter text.
Confirm data sharing agreement has been executed	☐ Yes, date executed: Click or tap here to enter text. ☐ No, reason: Click or tap here to enter text.
Additional comments:	Click or tap here to enter text.
Date of transfer:	Click or tap here to enter text.
Method of transfer:	Click or tap here to enter text.

_____ _____

Data Transfer Coordinator Signature ***Date (DD-MMM-YYYY)***